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Orally Disintegrating Tablets - Friendly to Pediatrics and Geriatrics

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Abstract

Orally disintegrating tablets (ODTs) have emerged as one of the popular and widely accepted dosage forms, especially for the pediatric and geriatric patients. To obviate the problem of dysphagia and to improve patient compliance, ODTs have gained considerable attention as preferred alternatives to conventional tablet and capsule formulations. Various scientific techniques including freeze drying, moulding, spray drying, sublimation, direct compression, cotton candy process, mass extrusion, melt granulation etc. have been employed for the development of ODTs. These techniques render the disintegration of tablet rapidly and dissolve in mouth without chewing or additional water intake. The current article is focused on ideal characteristics, significant features, patented technologies, formulation aspects including the use of superdisintegrants. Various marketed preparations along with numerous scientific advancements made so far in this avenue have also been discussed.

Keywords: Orally disintegrating tablets, Superdisintegrants, Disintegration, Enhanced bioavailability.

INTRODUCTION

Despite of tremendous innovations in drug delivery, the oral route remains the preferred route for administration of therapeutic agents because of accurate dosage, low cost therapy, self medication, non invasive method and ease of administration leading to high level of patient compliance [1, 2]. However, traditional tablets and capsules administered with a glass of water may be inconvenient or impractical for some geriatric patients because of changes in various physiological and neurological conditions associated with aging including difficulty in swallowing/dysphagia, hand tremors, deterioration in their eyesight, hearing, memory, risk of

choking in addition to change in taste and smell [3, 4]. For these reasons, it is said that age is a convenient 'red flag' that pharmacists can use to alert themselves for patients who may have special counseling needs [5]. Solid dosage forms also present significant administration challenges in other patient groups, such as children, mentally challenged, bed ridden and uncooperative patients. Pediatric patients may suffer from ingestion problems as a result of underdeveloped muscular and nervous control. Moreover, patients traveling with little or no access to water, limit utility of orally administered conventional tablets or capsules.

Therefore, to cater the needs of such patients, recent advancements in technology have resulted in development of viable dosage alternatives popularly known as orally disintegrating tablets (ODTs). These dosage forms are preferable alternative for oral medication in improving the quality of life and patient acceptability. ODTs are also known as orodispersible tablets, mouth dissolving tablets, rapimelts, melt-in-mouth tablets, fast disintegrating tablets and rapid dissolving tablets [6]. ODTs are the solid unit dosage forms/entities containing medicinal substances which disintegrate or dissolve rapidly in oral cavity usually within a few seconds even without the need of water or chewing. As the tablet disintegrates in mouth, this can enhance the clinical effect of drug through pregastric absorption from the mouth, pharynx and esophagus [7, 8]. In such cases, bioavailability of drug is significantly enhanced by avoiding first pass hepatic metabolism than those observed with conventional tablets. ODTs also combine the advantages of both liquid and conventional tablet formulations allowing the ease of swallowing in the form of liquid [3, 9]. The advantages of these dosage forms are continuously and increasingly being identified in both pharmaceutical industries as well as in academia. The objective of present article is to highlight the development of ODTs, their significance, ideal characteristics, various techniques and aspects related to design and formulation, marketed preparations and future prospectives.

Significance of ODTs [6, 10-13]

ODTs offer dual advantages of solid dosage forms and liquid dosage forms along with special features which include:

- **Accurate dosing:** Being unit solid dosage forms, provide luxury of accurate dosing, easy portability and manufacturing, good physical and chemical stability and an ideal alternative for pediatric and geriatric patients.
- **Enhanced bioavailability:** Bioavailability of drugs is enhanced due to absorption from mouth, pharynx and esophagus.
- **Rapid action:** Fast onset of therapeutic action as tablet gets disintegrated rapidly along with quick dissolution and absorption in oral cavity.
- **Patient compliance:** No need of water to swallow the dosage form. Hence, it is convenient for patients who are traveling and do not have immediate access to water.
- **Ease of administration:** Convenient to administer specially for geriatric, pediatric, mentally disabled and bed ridden patients who have difficulty in swallowing.
- **Obstruction free:** No risk of suffocation in airways due to physical obstruction when swallowed, thus providing improved safety and compliance.
- **Enhanced palatability:** Good mouth feel, especially for pediatric patients as taste masking technique is used to avoid the bitter taste of drug.

- **Simple packaging:** No specific packaging required. It can be packaged in push through blisters.
- **Business avenue:** Provide new business opportunities in the form of product differentiation, line extension, uniqueness and life cycle management.
- **Cost effective:** Conventional processing and packaging equipments allow the manufacturing of tablets at low cost.

Ideal characteristics of ODTs [6, 12, 14-16]

ODTs should depict some ideal characteristics to distinguish them from traditional conventional dosage forms. Important desirable characteristics of these dosage forms include:

- No water requirement for swallowing purpose but it should dissolve or disintegrate in the mouth usually within fraction of seconds.
- Provide pleasant feeling in the mouth.
- Be compatible with taste masking.
- Be portable without fragility concern.
- Leave negligible or no residue in the mouth after oral administration.
- Exhibit low sensitivity to altered environmental conditions such as humidity and temperature.
- Allow high drug loading.
- Adaptable and amenable to conventional processing and packaging equipment at nominal expense.

Various approaches employed in manufacture of ODTs

There are number of techniques generally employed in the formulation of orally disintegrating dosage forms. These techniques have their own advantages as well as disadvantages and are described below:

Direct compression

Direct compression is one of the popular techniques for preparation of these dosage forms. The advantages of this method include easy implementation, use of conventional equipments along with commonly available excipients, limited number of processing steps and cost effectiveness. Disintegration and solubilization of directly compressed tablets depend on single or combined action of disintegrants, water-soluble excipients and effervescent agents. The basic principle involved in development of these dosage forms using this technique is addition of superdisintegrants in optimum concentrations so as to achieve rapid disintegration along with pleasant mouth feel [17]. It is considered as the best method to prepare orally disintegrating dosage forms since the prepared tablets offer higher disintegration due to absence of binder and low moisture contents [18]. This approach is also considered as disintegrant addition technology. Bi *et al* and Watanabe *et al* developed fast-dissolving tablets using microcrystalline cellulose and low substituted hydroxy propyl cellulose as disintegrating agents in the range of 8:2-9:1 [19, 20]. Shu *et al* also prepared rapid oral disintegrating tablets by direct compression using co-ground mixture of D-mannitol and crospovidone [21].

Freeze drying

Freeze drying or lyophilization is a process in which solvent is removed from a frozen drug solution or suspension containing structure forming excipients. Tablets formulated by this technique are usually very light and porous in nature which allows their rapid dissolution. Glassy amorphous porous structure of excipients as well as the drug substance produced with freeze drying results in enhanced dissolution. Freeze drying process normally consists of three steps:

- Material is frozen to bring it below the eutectic point.
- Primary drying to reduce the moisture around 4% w/w of dry product.
- Secondary drying to reduce the bound moisture upto required final volume.

Entire freeze drying process is carried out at non elevated temperature; therefore, nullifying adverse thermal effects that may affect drug stability during processing [17]. R.P. Scherer patented *zydis technology* utilizing lyophilization or freeze drying process in development of mouth dissolving tablets on the basis of patents issued to Gregory *et al* [22, 23]. Corveleyn Sam *et al* also prepared rapidly disintegrating tablets by lyophilization [24].

Sublimation

Because of low porosity, compressed tablets containing highly water-soluble excipients as tablet matrix material often do not dissolve rapidly in water. Some inert volatile substances like urea, urethane, ammonium carbonate, naphthalene, camphor etc. are added to other tablet excipients and blend is compressed into tablet. Removal of volatile substances by sublimation generates a porous structure. Various steps involved in sublimation process are shown in Figure 1. Additionally several solvents like cyclohexane and benzene etc. can also be used as pore forming agents.

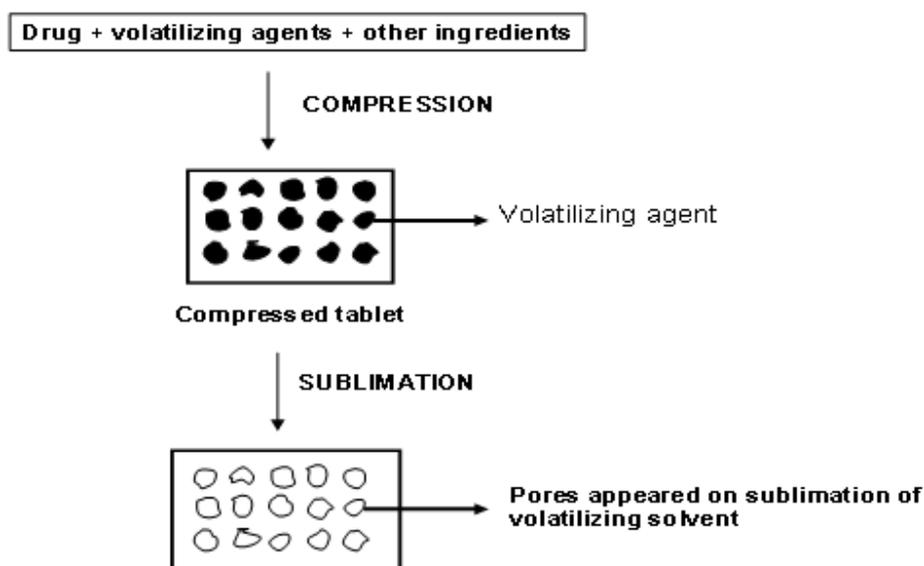


Figure 1: Steps involved in sublimation process

Koizumi *et al* formulated rapidly saliva soluble tablets using camphor as subliming agent. The tablets were subjected to vacuum at 80°C for 30 min. to eliminate camphor and thus create pores in the tablet. Porous tablet exhibits good mechanical strength and dissolve quickly [17, 25]. Gohel M. *et al* prepared mouth dissolving tablets of nimesulide using vacuum drying technique and found that it would be an effective alternative approach compared to the use of more expensive adjuvants in the formulation of these dosage forms [26].

Moulding

Moulded tablets are designed to facilitate the absorption of active ingredients through mucosal linings of mouth. This is achieved by complete and rapid dissolution of the tablet using water soluble ingredients. Moulded tablets disintegrate more rapidly and offer improved taste because of the dispersion matrix which is generally prepared from water soluble sugars. Powdered blend (containing drug and excipients like binding agents - sucrose, acacia, PVP etc.) is pushed through a very fine screen (to ensure rapid dissolution) and then moistened with a hydro-alcoholic solvent and moulded into tablets under pressure lower than employed for conventional compressed tablets. The solvent is later removed by air drying. A porous structure that enhances dissolution prepared by using water soluble ingredients meant to be absorbed through mucosal lining of mouth, thus increasing bioavailability and decreasing first pass metabolism of certain drugs. Vanscoik K.G. incorporated drug containing discrete particles formed by spray congealing a molten matrix of hydrogenated cottonseed oil, sodium bicarbonate, lecithin, polyethylene glycol and an active ingredient into a lactose based tablet triturate form. Upon oral administrations, the triturate tablet dissolved rapidly [17, 27].

Spray drying

This technique is based upon the use of a particulate support matrix prepared by spray drying an aqueous composition containing support matrix and other components to form a highly porous and fine powder. Allen *et al* utilized this process for preparing ODTs. These formulations consisted of hydrolyzed/unhydrolyzed gelatin as supporting agent for matrix, mannitol as bulking agent, and sodium starch glycolate or croscarmellose sodium as disintegrating agent. Disintegration and dissolution were further improved by adding effervescent components, i.e. citric acid and sodium bicarbonate. The formulation was finally spray dried to yield a porous powder [10, 28, 29].

Mass extrusion

This technology consist of softening the active blend using a solvent mixture of water soluble polyethylene glycol with methanol and expulsion of softened mass through the extruder or syringe to obtain cylinder of the product into even segments employing heated blade to form tablet. The dried cylinder can also be utilized for coating the granules of bitter drugs and thereby masking their taste [10, 30].

Cotton candy process

This process is so named as it utilizes an inimitable spinning mechanism to produce floss like crystalline structure, which mimics cotton candy. This technique involves formation of matrix of polysaccharides or saccharides by simultaneous action of flash melting and spinning. The matrix formed is partially recrystallized to have better flow properties and compressibility. This matrix

is milled and blended with active ingredients as well as excipients and subsequently compressed to ODTs. This process can accommodate high doses of drug and offers improved mechanical strength. However, high process temperature limits the use of this process [10, 31].

Phase transition

Kuno *et al* proposed a novel method to prepare ODTs with sufficient hardness by involving the phase transition of sugar alcohol. In this technique, ODTs are produced by compressing and subsequently heating tablets that contain two sugar alcohols, one with high and other with a low melting point. Heating process enhances the bonding among particles leading to sufficient hardness of tablets which was otherwise lacking owing to low/little compactibility [32].

Melt granulation

Melt granulation is a process in which pharmaceutical powders are efficiently agglomerated by the use of binder which can be a molten liquid, a solid or a solid that melts during the process. For accomplishing this process, high shear mixers are utilized, where the product temperature is raised above the melting point of binder by a heating jacket or by the heat of friction generated by impeller blades. Perissutti *et al* prepared carbamazepine fast-release tablets by melt granulation technique using polyethylene glycol 4000 as a melting binder and lactose monohydrate as hydrophilic filler [33, 34].

Patented technologies [1, 11, 35-44]

Rapid-dissolving characteristic of ODTs is generally attributed to quick penetration of water into tablet matrix resulting in its fast disintegration. Several technologies have been developed on the basis of formulation aspects and different processes. Resulting dosage forms vary on several parameters like mechanical strength, porosity, dose, stability, taste, mouth feel, dissolution rate and overall bioavailability. Table 1 represents the list of unique patented technologies, their scientific basis, patent owner along with significant advantages.

Table 1: Various patented technologies

| Patented Technology | Technique Employed | Company Name | Active Ingredient (Brand Names) | Advantage(s) |
|---------------------|--------------------|---------------------|--|---|
| Zydis | Lyophilization | R.P. Scherer, Corp. | Loratidine (Claritin Reditab and Dimetapp Quick Dissolve) | Highly porous in nature, quick dissolution, increased bioavailability |
| Quicksolv | Lyophilization | Janssen Pharma | Cisapride monohydrate (Propulsid Quicksolv), Risperidone (Risperdal M- | Short disintegration time, good mouthfeel |

| | | | Tab) | |
|-----------|--|------------------------------|--|--|
| Lyoc | Lyophilization | Farmalyoc | Phloroglucinol Hydrate (Spasfon Lyoc) | Accommodate high dose, disintegrates rapidly |
| Orasolv | Effervescent disintegrant compression | CIMA Labs, Inc. | Paracetamol (Tempra Quicklets), Zolmitriptan (Zolmig Repimelt) | Unique taste masking, fast dissolution, require conventional manufacturing process |
| Durasolv | Molding | CIMA Labs, Inc. | Hyoscyamine Sulfate (NuLev) Zolmitriptan (Zolmig ZMT) | Good rigidity |
| Wowtab | Compression molded tablets | Yamanouchi Pharma Tech. Inc. | Famotidine (Gaster D) | Adequate dissolution rate and hardness |
| Flashdose | Cotton Candy Process | Fuisz Technology Ltd. | Tramadol HCl (Relivia Flash dose) | Highly porous in nature, pleasant mouthfeel |
| Flashtab | Effervescent disintegrant microencapsulated drug compression | Prographarm Group | Ibuprofen (Nurofen FlashTab) | Conventional tableting technology required |
| Ziplets | Molding | Eurand International | Ibuprofen (Cibalgina DueFast) | Sufficient mechanical strength |
| Oraquick | Micromask taste masking | KV Pharm. Co., Inc. | Hyoscyamine Sulfate ODT | Significant friability, appropriate for thermolabile drugs |
| Advatab | Microcaps and diffuscap CR Technology | Eurand International | AdvaTab cetirizine, AdvaTab Paracetamol | High drug loading, improved mechanical strength |

Superdisintegrants

Disintegrants are substances routinely included in tablet formulations and in some hard shell capsule formulations to promote moisture penetration and dispersion of the matrix of dosage

form in dissolution fluids. An oral solid dosage form should ideally disperse into the primary particles from which it was prepared [45]. Superdisintegrants are generally used at a low concentration, typically 1-10% by weight relative to total weight of dosage unit. Generally employed superdisintegrants are croscarmellose sodium (Ac-Di-Sol), crospovidone (CP), sodium starch glycolate (SSG) etc. which represent example of crosslinked cellulose, crosslinked polymer and crosslinked starch respectively.

Selection of appropriate formulation excipients and manufacturing technology is necessary for obtaining the optimized design features of orally disintegrating dosage forms. Ideally, superdisintegrants should cause the tablet to disrupt, not only into the granules from which it was compressed but also into powder particles from which the granules were prepared [46].

Selection of superdisintegrants [47]

Although superdisintegrants primarily affect the rate of disintegration, but when used at high levels they can also affect mouth feel, tablet hardness and friability. Hence, various ideal factors to be considered while selecting an appropriate superdisintegrants for a particular formulation should:

- Produce rapid disintegration, when tablet comes in contact with saliva in the mouth/oral cavity.
- Be compactable enough to produce less friable tablets.
- Produce good mouth feel to the patients. Thus, small particle size is preferred to achieve patient compliance.
- Have good flow, since it improves the flow characteristics of total blend.

Mechanism of action of disintegrant [1, 45, 48-51]

Various mechanisms proposed in this concern include water wicking, swelling, deformation recovery, repulsion and heat of wetting. It seems likely that no single mechanism can explain the complex behavior of the disintegrants. However, each of these proposed mechanisms provides some understanding of different aspects of disintegrant action.

Water wicking

The ability of disintegrant to draw water into the porous network of tablet is essential for effective disintegration. On keeping the tablet into suitable aqueous medium, the medium enters into tablet and replaces the air adsorbed on the particles which weakens the intermolecular bonds and breaks the tablet into fine particles. Water uptake by tablet depends upon hydrophilicity of the drug/excipients and on tableting conditions. Unlike swelling, which is mainly a measure of volume expansion with accompanying force generation, water wicking is not necessarily accompanied by a volume increase. The ability of a system to draw water can be summarized by Washburn's equation:

$$L^2 = (\gamma \cos\theta/2\eta) \times rt$$

The Washburn equation is too simplistic to apply to a dynamic tablet-disintegration process, but it does show that any change in the surface tension (γ), pore size (r), solid-liquid contact angle (θ) or liquid viscosity (η) could change the water wicking efficiency. L is the length of water

penetration in the capillary and t is the time. This process is also considered as capillary action method.

Swelling

Although water penetration is a necessary first step for disintegration, swelling is probably the most widely accepted mechanism of action for tablet disintegrants. For swelling to be effective as a mechanism of disintegration, there must be a superstructure against which disintegrant swells. Figure 2 represents the disintegration of tablet by wicking and swelling. Swelling of the disintegrant against the matrix leads to development of a swelling force. A large internal porosity in the dosage form in which much of the swelling can be accommodated reduces the effectiveness of the disintegrant. On the other hand, sufficient swelling force is exerted in the tablet with low porosity. It is worthwhile to note that if packing fraction is very high, fluid is unable to penetrate in the tablet and disintegration is again slowed down.

Heat of wetting

When disintegrants with exothermic properties get wetted, localized stress is created due to capillary air expansion, which aids in disintegration of tablet. This explanation, however, is limited to only a few types of disintegrants and can not describe the action of most modern disintegrating agents.

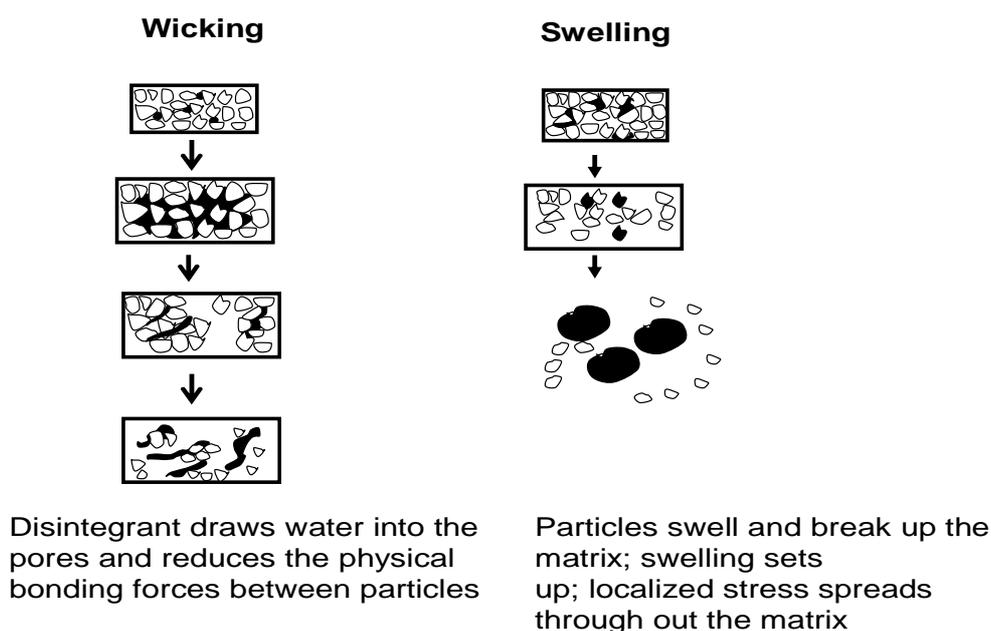


Figure 2: Disintegration of tablet by wicking and swelling

Due to release of gases

Carbon dioxide gets released within tablets on wetting due to interaction between bicarbonate and carbonate with citric acid or tartaric acid. The tablet disintegrates due to generation of pressure within the tablet. This effervescent mixture is used when pharmacist needs to formulate

very rapidly dissolving tablets or fast disintegrating tablet. As these disintegrants are highly sensitive to small changes in humidity level and temperature, strict control of environment is required during preparation of the tablets. The effervescent blend is either added immediately prior to compression or can be added into two separate fractions of formulation.

Particle repulsive forces

This is another mechanism of disintegration that attempts to explain the swelling of tablet made with non-swelling disintegrants. Guyot-Hermann proposed a particle-particle repulsion theory to explain the observation that particles which do not swell extensively such as starch, could still disintegrate tablets. According to this theory, water penetrates into tablet through hydrophilic pores and a continuous starch network is created that can convey water from one particle to the next, imparting a significant hydrostatic pressure. The water then penetrates between starch grains because of its affinity for starch surfaces, thereby breaking hydrogen bonds and other forces holding the tablet together. The electric repulsive forces between particles are the mechanism of disintegration and water is required for it.

Deformation recovery

Deformation recovery theory implies that the shape of disintegrant particles is distorted during compression and the particles return to their precompression shape upon wetting, thereby causing the tablet to break apart. Such a phenomenon may be an important aspect of the mechanism of action of disintegrants such as croscovidone and starch that exhibit little or no swelling. Disintegration of tablet by deformation as well as repulsion is illustrated in Figure 3.

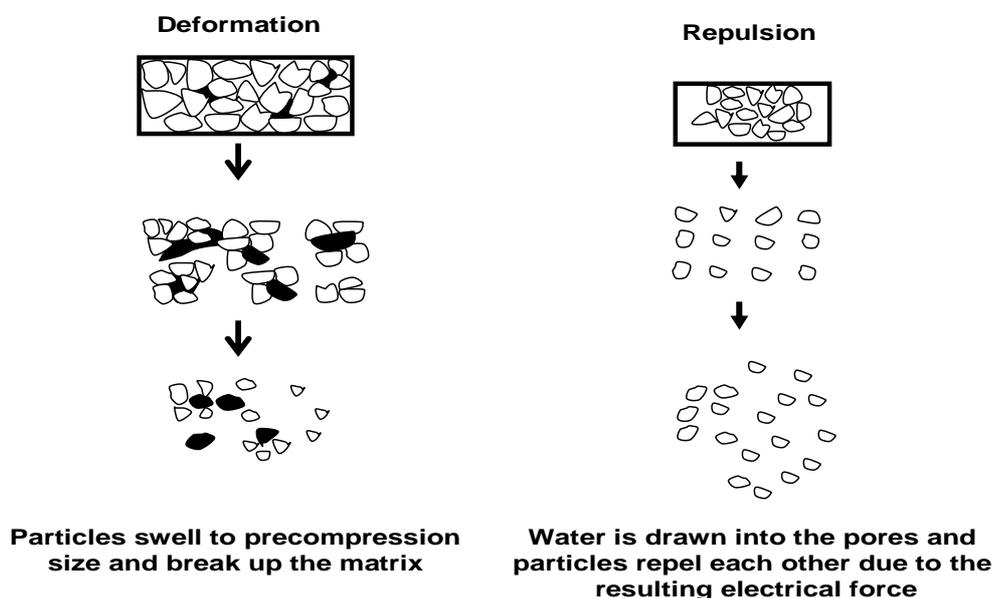


Figure 3: Disintegration by deformation and repulsion

By enzymatic reaction

Enzymes present in the body also act as disintegrants. These enzymes dearth the binding action of binder and helps in disintegration. Due to swelling, pressure is exerted in the outer direction

that causes the tablet to burst or the accelerated absorption of water leads to an enormous increase in the volume of granules to promote disintegration.

Selection of drug candidates for ODTs [52]

Several factors must be considered while selecting an appropriate drug candidate for development of orally disintegrating dosage forms. The ultimate characteristics of a drug for dissolution in the mouth and pregastric absorption from ODTs include:

- Free from bitter taste.
- Dose lower than 20 mg.
- Small to moderate molecular weight.
- Good solubility in water and saliva.
- Partially nonionized at the oral cavity's pH.
- Ability to diffuse and partition into the epithelium of the upper GIT ($\log P >1$, or preferably >2).
- Ability to permeate oral mucosal tissue.

In contrast, the following characteristics may render a drug unsuitable for delivery as an orally disintegrating dosage form:

- Short half-life and frequent dosing.
- Very bitter or otherwise unacceptable taste because taste masking cannot be successfully achieved.
- Require controlled or sustained release.
- Combination with anticholinergics.

Wide range of drugs can be considered as a suitable candidate for such dosage forms. Various researchers have developed orally disintegrating dosage forms for different categories of drugs used in clinical therapy in which rapid peak plasma concentration is required to achieve the desired pharmacological response. These include neuroleptics, cardiovascular agents, analgesics, antiallergics, antiepileptics, anxiolytics, sedatives, hypnotics, diuretics, antiparkinsonism agents, antibacterial agents etc.

Marketed preparations of ODTs [53, 54]

Now a day, ODTs are gaining more and more popularity and acceptability in the pharmaceutical market. These dosage forms entered the market in 1980s, have grown steadily in demand, and their product pipelines are swiftly expanding. Currently these tablets are available in the market for many ailments. Some of the commercially available orally disintegrating dosage forms are summarized in Table 2.

Table 2: List of commercially available ODTs

| Product Name | Active Ingredient | Category | Manufacturer |
|---------------------|--------------------------|-------------------------|--|
| Abilify Discmelt | Aripiprazole | Atypical antipsychotics | Otsuka America Pharmaceuticals Inc./Bristol-Myers Squibb Co. |
| Alavert ODT | Loratadine | Anti-histamines | Wyeth Consumer |

| | | | |
|----------------------------|----------------------|--|-----------------------------|
| | | | Healthcare |
| Allegra ODT | Fexofenadine | Anti-histamines | Sanofi Aventis |
| Aricept ODT | Donepezil | Acetylcholinesterase inhibitors | Eisai Inc. |
| Benadryl Allergy Fast Melt | Diphenhydramine | Anti-histamines & anticholinergic | Pfizer Consumer Healthcare |
| Calpol Fast Melts | Paracetamol | Analgesics | McNeil Healthcare |
| Cibalginadue FAST | Ibuprofen | NSAIDs | Novartis Consumer Health |
| Clarinox RediTabs | Desloratadine | Anti-histamines | Schering-Plough Corporation |
| Claratin RediTabs | Loratadine | Anti-histamines | Schering-Plough Corporation |
| Clonazepam ODT | Clonazepam | Benzodiazepines (Anxiety, Seizure Disorders) | PAR Pharmaceuticals |
| Feldene fast melt | Piroxicam | NSAIDs | Pfizer Consumer Healthcare |
| Manza RDT | Olanzapine | Antipsychotic | Mano Pharma |
| Maxalt-MLT | Rizatriptan | Triptans/Serotonin | Merck & Co. |
| Mirtazapine ODT | Mirtazapine | Antidepressant | Teva Pharmaceuticals |
| Mosid MT | Mosapride | 5HT ₄ agonist | Torrent Pharmaceuticals |
| Nency MD | Nimesulide | Antipyretic | Zenon Health Care |
| Nexus MD | Nimesulide | Antipyretic | Lexus Pharmaceuticals |
| Nimpain MD | Nimesulide | Antipyretic | Prompt Cure Pharm |
| Nimulid-MD | Nimesulide | Antipyretic | Panacea Biotech |
| Nulev | Hyoscyamine sulphate | Anticholinergic | Schwarz Pharma |
| Ondansetron ODT | Ondansetron | Antiemetics | Teva Pharmaceuticals |
| Pepcid RPD | Famotidine | Antihistamine | Merck & Co. |
| Reglan ODT | Metoclopramide | Antiemetics | Schwarz Pharma |
| Romilast | Montelukast | Antiasthmatic | Ranbaxy Labs Ltd |
| Zofran ODT | Ondansetron | Antiemetics | GlaxoSmithKline |
| Zolpidem ODT | Zolpidem | Hypnotics | Biovail Pharmaceuticals |
| Zotacet MD | Cetirizine HCl | Antihistamine | Zota Pharma |

CONCLUSION

ODTs offer numerous significant advantages over conventional dosage forms because of improved efficacy, bioavailability, rapid onset of action, better patient compliance and acceptance. Pediatric and geriatric patients are primary concerns, as both the groups find these dosage forms convenient to administer as compared to the conventional dosage forms. ODTs can be prepared in several ways and product performance depends upon the drug suitability and excipients selection in the delivery system. Due to the availability of various formulation techniques, good patient compliance and huge potential, several products have already been commercialized. Furthermore, market size and popularity of these dosage forms will surely expand in future. It is also emphasized that newer scientific and technological innovations should be undertaken for the emergence of promising and versatile dosage form with novel performance and characteristics.

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